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10/801,355

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Thomas S. Wilson

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EXAMINER

SONNETT, KATHLEEN C

ART UNIT

PAPER NUMBER

3731

MAIL DATE

DELIVERY MODE

10/17/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/801,355

Applicant(s)

WILSON ET AL.

Examiner

Kathleen Sonnett

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 July 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-56 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-56 is/are rejected.
- 7) ☒ Claim(s) 3 and 25 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

1. Claims 3 and 25 are objected to because of the following informalities: ratios are unitless and it appears that the expansion ratio is actually 2 to 200 (which results in an expansion of between 200 and 20,000 percent). Appropriate correction is required.

Double Patenting

2. Applicant is advised that should claim 1 be found allowable, claims 21 and 22 will be objected to under 37 CFR 1.75 as being substantial duplicates thereof; should claim 23 be found allowable, claims 43 and 44 will be objected to under 37 CFR 1.75 as being substantial duplicates thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. **Claims (1, 21, 22, 23, 43, 44), 45, 51, and 52** are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims (4), 19, and 20, and 21 of copending Application No. 10/781,582 (as amended in the last filed amendment to the claims on 12/13/06. Although the conflicting claims are not identical, they are not patentably distinct from each other because the scope of the claims of copending Application No.

10/781,582 is narrower and therefore anticipates the broader claims of the instant application (1-5 and 8). It is also noted that the language appearing in the preamble regarding the physical anomaly is functional language and a shape memory polymer foam capable of closing a gap in a vascular wall is capable of closing an aneurysm.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

4. Claims (3, 4, 25) are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 4 of copending Application No. 10/781,582 in view of Bleys et al. (US 6,034,149). Claim 4 of '582 claims the invention substantially but fails to claim that the foam is an open celled polyurethane with an expansion ratio in the range of 2 to 200. However, Bleys teaches such a shape memory polymer foam with the above mentioned properties and it would have been obvious to one skilled in the art to use a shape memory polymer with similar properties to that of Bleys since the foam is well suited for medical applications due to its low level of leachable substances (see col. 6, ll. 46-51).

This is a provisional obviousness-type double patenting rejection.

5. Claims (2 and 24) are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 4 of copending Application No.

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10/781,582 in view of Picha (US 5,207,709). Claim 4 of '582 claims the invention substantially but fails to claim that the foam is open celled with pores of between 10 microns and 50 microns. However, Picha teaches that a pore size of 10 to 50 microns is advantageous on implantable foam because it induces blood vessel proximity and neovascularization of the implant (col. 8, ll. 41-46). It would have been obvious to size the open cells of the shape memory foam of '582 so that the pores are between 10 and 50 microns since Picha teaches that such pore sizes allows tissue ingrowth.

This is a provisional obviousness-type double patenting rejection.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. **Claims 1, 3, 4, 6-15, 21-23, 25-37, 43, and 44** are rejected under 35 U.S.C. 103(a) as being unpatentable over Maitland et al. (2002/0095169) in view of Bleys et al. (US 6,034,149). Maitland et al. discloses an apparatus for occluding a physical anomaly comprising a shape memory polymer for positioning in the interior of the physical anomaly and a system for providing the shape memory polymer with a primary shape for occluding the physical anomaly and a secondary shape for being positioned in interior of the physical anomaly (see abstract). The apparatus also comprises a delivery system (30 and 32 or 12) capable of delivering the shape memory material body into the interior of the physical anomaly. Maitland fails to disclose that the shape memory material body comprises a shape memory polymer foam.

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8. Foams are well known in the art for forming occlusions or sealing holes in the body to ensure that liquid cannot escape and are an obvious, known alternative form for occlusive materials. Furthermore, Bleys et al. discloses foam that has shape memory properties, is flexible, and has a minimum amount of leachable substances, which makes the foam especially useful in medical applications (col. 6, ll. 46-51). It would have been obvious to one of ordinary skill in the art to modify the device of Kamiya et al. to choose the shape memory foam of Bleys et al. for the shape memory material body because foams are well known in the medical art for use in occluding and sealing holes in the body and the foam of Bleys includes shape memory characteristics while having improved biocompatibility from other foams because of its minimum amount of leachable substances (col. 6 ll. 45-51).

9. Regarding claims 3, 4, and 25, the shape memory foam taught by Bleys is a polyurethane open cell foam. Bleys discloses that the compressed shape size is at most 60% of the expanded shape size. At most 60% percent means Bleys teaches any value less than 60%. For example, if the compressed shape size is about 33% of the expanded shape size, then the foam expands by about 200% (*200% increase*) to go from the compressed shape to the expanded shape. (Please see claim objections above).

10. Regarding claims 6 and 26, the shape memory foam has a light absorbing dye [0075].

11. Regarding claims 7, 27-29, and 33, the apparatus includes a delivery catheter (30) and a guide wire (32). The shape memory material is at the end of the guide wire.

12. Regarding claims 12, 13, 34, and 35, Maitland et al. discloses a system for providing the shape memory material with a primary and secondary shape comprising a system for optical heating using optic fibers to transport light (laser) energy to the shape memory material body through the optical fiber (see [0059], [0062]).

13. Regarding claims 14 and 36, the optical fiber may be multimode ([0061]).

14. Regarding claims 15 and 37, the shape memory material comprises a light absorbing material ([0059]).

15. Regarding claims 21 and 43, the shape memory material has a primary shape that is larger than a secondary shape (see fig. 1 and 2).

16. Regarding claims 11 and 33, modified Maitland et al. discloses a shape memory polymer foam connected at the end of the guidewire (see fig. 7).

17. Regarding claims 8-10 and 30-32, Maitland et al. discloses a system for providing the shape memory body with a primary and secondary shape comprising electromagnetic energy delivered optically (which is a form of radiation) (see [0057]).

18. **Claims 1, 3, 7, 21-23, 25, 27-29, 43-45, 47, and 49** are rejected under 35 U.S.C. 103(a) as being unpatentable over Kamiya et al. (U.S. 5,192,301) in view of Bleys. Kamiya et al. discloses an apparatus for occluding a physical anomaly comprising a shape memory polymer for positioning in the interior of the physical anomaly and a system for providing the shape memory polymer with a primary shape for occluding the physical anomaly and a secondary shape for being positioned in interior of the physical anomaly (see abstract). The apparatus also comprises a delivery system (12 and 13) capable of delivering the shape memory material body into the interior of the physical anomaly. Kamiya fails to disclose that the shape memory material body comprises a shape memory polymer foam.

19. Foams are well known in the art for forming occlusions or sealing holes in the body to ensure that liquid cannot escape. Bleys et al. discloses foam that has shape memory properties, is flexible, and has a minimum amount of leachable substances, which makes the foam especially useful in medical applications. It would have been obvious to one of ordinary skill in the art to modify the device of Kamiya et al. to choose the shape memory foam of Bleys et al. for the shape memory material body because of its biocompatibility (col. 6 ll. 45-51).

20. Regarding claims 3, 4, and 25, the shape memory foam taught by Bleys is a polyurethane open cell foam. Bleys discloses that the compressed shape size is at most 60% of the expanded shape size. At most 60% percent means Bleys teaches any value less than 60%. For example, if the compressed shape size is about 33% of the expanded shape size, then the foam expands by about 200% to go from the compressed shape to the expanded shape.

(Please see claim objections above).

21. Regarding claims 7, 27-29, and 49, the apparatus includes a delivery catheter (22) and a guide wire (23). The shape memory material is at the end of the guide wire (see fig. 27).

22. Regarding claims 21 and 43, the shape memory material has a primary shape that is larger than a secondary shape (see abstract). This is capable of occluding an anomaly.

23. Regarding claims 45 and 47, Kamiya et al. in view of Bleys discloses a method of occluding a physical anomaly, the physical anomaly having an interior comprising the steps of providing a shape memory material body comprising a shape memory polymer foam with a secondary shape for being positioned in the interior of a physical anomaly, positioning the body in the anomaly when in its secondary shape, and causing the body to change to a larger primary shape for occlusion (see abstract). A catheter is used to position the shape memory body in the interior of the anomaly in its secondary shape (see col. 7 ll. 66-col. 8 ll. 30).

24. **Claims 2 and 24** are rejected under 35 U.S.C. 103(a) as being unpatentable over Maitland et al. in view of Bleys as applied to claims 1 and 23, and further in view of Picha (US 5,207,709). Maitland in view of Bleys discloses the invention substantially as stated above including that the polymer foam has an open cell foam structure, but fails to expressly disclose the pore size.

25. However, Picha teaches that a pore size of 10 to 50 microns is advantageous on implantable foam because it induces blood vessel proximity and neovascularization of the

implant (col. 8, ll. 41-46). It would have been obvious to size the open cells of the shape memory foam of Maitland in view of Bleys so that the pores are between 10 and 50 microns since Picha teaches that such pore sizes allows tissue ingrowth.

26. **Claims 2, 24, and 46** are rejected under 35 U.S.C. 103(a) as being unpatentable over Kamiya et al. in view of Bleys as applied to claims 1, 23, and 45 above, and further in view of Picha (US 5,207,709). Kamiya in view of Bleys discloses the invention substantially as stated above including that the polymer foam has an open cell foam structure, but fails to expressly disclose the pore size.

27. However, Picha teaches that a pore size of 10 to 50 microns is advantageous on implantable foam because it induces blood vessel proximity and neovascularization of the implant. It would have been obvious to size the open cells of the shape memory foam of Kamiya in view of Bleys so that the pores are between 10 and 50 microns since Picha teaches that such pore sizes allows tissue ingrowth.

28. **Claim 5** is rejected under 35 U.S.C. 103(a) as being unpatentable over Kamiya in view of Bleys as applied to claim 1 above, and further in view of Linden et al. (US 5,634,936). Kamiya in view of Bleys discloses the invention substantially as stated above including that the shape memory polymer is an open-celled polyurethane foam but fails to disclose the foam being a ten percent solution in dimethyl sulfoxide (DMSO).

29. However, Linden teaches using DMSO as a solvent with a foam used to occlude a hole in tissue. Solvents such as DMSO can be used to keep the foam soft prior to hardening it once it has been deployed within a tissue defect. This hardening can be affected to changing the solution or by cooperative effects between the patient's blood and the foam. It would have been obvious to one skilled in the art to modify the device of Kamiya to include dissolving the polymer foam within solution of DMSO since Linden teaches that such solvents paired with foams are

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well known and can be used to keep the foam soft prior to deployment. Regarding the claimed 10 percent solution, it has been held that discovering an optimum value of a result effective variable, in this case the amount of polymer dissolved in the DMSO, involves only routine skill in the art (*In re Boesch*, 617 F.2d 272, 205 USPO 215 (CCPA 1980)).

30. **Claims 17-20 and 39-42** are rejected under 35 U.S.C. 103(a) as being unpatentable over Kamiya et al. or Maitland et al. in view of Bleys as discussed above and further in view of Porter (US 2002/0165582). Kamiya and Maitland et al. in view of Bleys both disclose the invention substantially as stated above, but fail to disclose that the system for providing the shape memory material with two different shapes comprises microparticles or nanoparticles that can selectively absorb RF radiation converting it to heat.

31. However, Porter discloses that it is old and well known to provide microparticles in a substance used to fill any site in the human body ([0011], [0018], [0085]). These particles selectively absorb RF radiation, converting it to heat. The shape memory polymer of Maitland et al. is heated to cause the shape memory polymer to change shape and providing the microparticles of Porter would provide an advantageous means of heating because the small magnetic particles are a point heat source and do not cause significant tissue damage around the implantation site [0082]. Kamiya et al. is silent regarding how the shape memory body is heated and the disclosure of Porter teaches an appropriate method to achieve such heating of the device. Therefore, it would have been obvious to one of ordinary skill in the art to modify the device of Maitland et al. or Kamiya et al. to include magnetic microparticles as made obvious by Porter in order to have a convenient point heat source and the use of a shape memory foam with a higher transition temperature.

32. Regarding the use of nanoparticles, applicant has not disclosed that nanoparticles are used for any particular purpose, provide any advantage or solve a particular problem as

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compared to the use of microparticles. Furthermore, it would appear to one of ordinary skill in the art that the instant device and modified Maitland et al. would perform equally well with the claimed nanoparticles or the microparticles as taught by Porter. Therefore, it would be prima facie obvious to use the claimed nanoparticles instead of the microparticles because they are considered an obvious design choice that fails to patentably distinguish over the prior art of Maitland et al. in view of Porter.

33. **Claims 48 and 50-52** are rejected under 35 U.S.C. 103(a) as being unpatentable over Kamiya et al. in view of Bleys as applied to claim 45 above and further in view of Maitland et al. Kamiya et al. discloses the method substantially as stated above, but fails to disclose using a laser and optical fiber to transmit laser light through the optical fiber.

34. However, Maitland et al. discloses that it is old and well known in the art to use optical fibers and lasers to heat a shape memory polymer such that it takes a larger primary shape. Kamiya et al. discloses that the plug is warmed to change shape but is silent on how this is achieved and Maitland et al. provides a heating method that does will not cause trauma to the surrounding tissue. Therefore, it would have been obvious to one of ordinary skill in the art to modify the method of Kamiya et al. to include using an optical fiber and laser to transmit laser light through the optical fiber to heat the shape memory body without causing surrounding trauma.

35. **Claims 53-56** are rejected under 35 U.S.C. 103(a) as being unpatentable over Kamiya et al. in view of Bleys as applied to claim 45 above and further in view of Porter. Kamiya et al. discloses the method substantially as stated above, but fails to disclose providing a shape memory foam that has microparticles or nanoparticles of a material which can selectively absorb RF radiation converting it to heat.

36. As mentioned above, Kamiya is silent on how the shape memory body is warmed and Porter teaches the use of magnetic microparticles dispersed in a polymer that can selectively absorb RF radiation converting it to heat. These microparticles provide point sources of heat that do not cause significant tissue damage around the implantation site [0082]. Providing such a system in the body of Kamiya et al. would allow the use of materials with transition temperatures further away from body temperature without damage to tissue. Therefore, it would have been obvious to one of ordinary skill in the art to modify the device of Maitland et al. or Kamiya et al. to include magnetic microparticles as made obvious by Porter in order to have a convenient point heat source and to be able to use of a shape memory material with a higher transition temperature.

37. Regarding the use of nanoparticles, applicant has not disclosed that nanoparticles are used for any particular purpose, provide any advantage or solve a particular problem as compared to the use of microparticles. Furthermore, it would appear to one of ordinary skill in the art that the instant device and modified Maitland et al. would perform equally well with the claimed nanoparticles or the microparticles as taught by Porter. Therefore, it would be prima facie obvious to use the claimed nanoparticles instead of the microparticles because they are considered an obvious design choice that fails to patentably distinguish over the prior art of Maitland et al. in view of Porter.

38. **Claims 16 and 38** are rejected under 35 U.S.C. 103(a) as being unpatentable over Maitland et al. Maitland et al. discloses the invention substantially as stated above including that the shape memory material body comprises a light absorbing material. Maitland et al. fails to expressly disclose that the shape memory material comprises a light absorbing dye in an elastomeric coating. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to provide a light absorbing elastomeric

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coating instead of a light absorbing material because Applicant has not disclosed that the elastomeric coating provides an advantage, is used for a particular purpose, or solves a stated problem over the use of a light absorbing material. One of ordinary skill in the art, furthermore, would have expected Maitland's material and applicant's invention, to perform equally well with either the material taught by Maitland et al. or the claimed coating because both perform the same function of absorbing light equally well.

39. Therefore, it would have been prima facie obvious to modify Maitland et al. to obtain the invention as specified in claims 16 and 38 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Maitland et al.

Response to Arguments

40. Applicant's arguments filed 7/25/2007 have been fully considered but they are not persuasive. Applicant argues that the combinations of Kamiya with Bleys et al. and Maitland with Bleys et al. fail to disclose the claimed invention. Applicant also argues that there is no motivation to combine either Kamiya or Maitland with the teachings of Bleys. However, both Kamiya and Maitland disclose a shape memory material for positioning in the interior of a physical anomaly. As mentioned above, foams are well known for use as materials that occlude or fill defects and holes found within a patient's body and it would have been obvious to one skilled in the art to try other known alternative materials for filling defects. Furthermore, Bleys teaches the use of a shape memory polymer foam that is flexible and has a minimum amount of leachable substances (col. 6, ll. 46-51). Bleys discloses that these properties make the foam especially useful in medical applications and one skilled in the art would have been motivated to

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use the foam of Bleys in the device of Kamiya or Maitland since the foam of Bleys is particularly suited for medical applications.

41. The additional limitation of shape memory polymer being foam overcomes the previously presented 35 USC 102(b) rejections over Maitland et al. and Kamiya et al.

42. The provisional obvious-type double patenting rejections have been updated to reflect the most recent amendment to the claims of copending application 10/781,582 as filed 9/21/2007.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen Sonnett whose telephone number is 571-272-5576. The examiner can normally be reached on 7:30-5:00, M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KCS 10/9/2007


GLENN K. DAWSON
PRIMARY EXAMINER